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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/065,286

09/30/2002

Christian A. Beck

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7590

05/17/2004

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EXAMINER

ROGERS, DAVID A

ART UNIT

PAPER NUMBER

2856

DATE MAILED: 05/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/065,286

Applicant(s)

BECK, CHRISTIAN A.

Examiner

David A. Rogers

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 January 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17:2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. The USPTO is in the process of moving to new office spaces in Alexandria, Virginia. Please note the new phone numbers for the examiner and the examiner's supervisor below.

Response to Arguments

2. In view of the appeal brief filed on 12 April 2004, PROSECUTION IS HEREBY REOPENED. The office apologizes for any inconvenience that this might have caused. New grounds of rejection are set forth below. To avoid abandonment of the application, appellant must exercise one of the following two options:

- (1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,
- (2) request reinstatement of the appeal.

If reinstatement of the appeal is requested, such request must be accompanied by a supplemental appeal brief, but no new amendments, affidavits (37 CFR 1.130, 1.131 or 1.132) or other evidence are permitted. See 37 CFR 1.193(b)(2).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary

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skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1, 2, 6, and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over United States Patent United States Patent 6,524,846 to Robinson, Jr., United States Patent Application Publication 2004/0046009 to Weisenberg *et al.*, United States Patent Application Publication 2003/0140015 to Applebaum, and/or United States Patent Application Publication 2003/0085266 to Simon, along with United States Patent 6,295,506 to Heinonen *et al.*, United States Patent Application Publication 2002/0072733 to Flaherty, and United States Patent Application Publication 2002/0083022 to Algazi.

Robinson, Jr. teaches an envelope (reference item 20) comprising a bio-hazardous material indicator (reference item 10) with a coated substrate (reference item 12) on a transparent holder (reference item 17). The transparent holder is mounted on a hole (window) (reference item 13) on a front side the envelope so that it is visible to the human eye. The bio-hazardous material indicator coating has a pH between 2 and 5 and is capable of, *inter alia*, detecting the gaseous amines released by *Bacillus anthracis* (anthrax) and will change color accordingly. Finally, Robinson, Jr. teaches that

"Other envelopes 20 in accordance with the principles relating to the present invention must be sorted manually and it is unimportant as to where the bacterial biological agent/toxin indicator 10 is located except that it must be in communication with the interior 19 of the envelope 20 and visible from an exterior of the same."

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Robinson, Jr., however, does not expressly teach the use of an envelope with a plurality of holes.

It is known in envelope manufacturing to provide the envelopes with a plurality of holes. The plurality of holes allows the user to easily determine if there are any remaining contents, e.g. letters, papers, etc., remaining inside prior to disposal. One can see exemplary examples of these types of envelopes in Weisenberg *et al.* (see figures 5a-10); Applebaum (see figures 2-4, 7, 9, and 10); and Simon (see figure 5). Furthermore, it is noted to the applicant that the Government, among others, has employed inter-office envelopes for decades. These envelopes also comprise a plurality of holes located on the front side and back side. See the below for a representative figure.

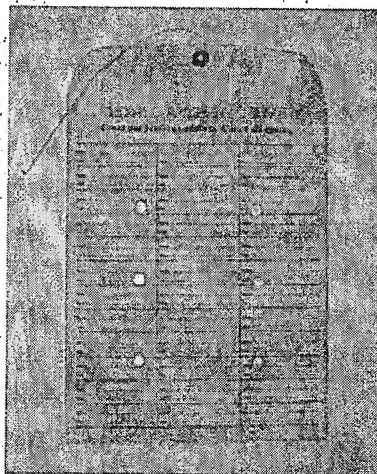


Figure 1 - Standard Interoffice envelope

Robinson, Jr. also teaches that the bio-hazardous material indicator will comprise an electronic fingerprint (reference item 16) representing an electronic code that is machine readable. Robinson, Jr., does not teach the use of a bio-hazardous material indicator (test strip) that includes an identifier associated

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with time data. Heinonen *et al.* teaches a test strip (reference item 5) for use in analyzing biological properties of a sample. The test strip of Heinonen *et al.* is taught as having a barcode (reference item 7) that is used to identify the manufacturing batch number. Knowing manufacturing information of the test strip would be desirable in case random sampling of the test strips, e.g. for quality control purposes, shows that certain batches are not providing the correct results and, therefore, must be removing from the marketplace.

Flaherty teaches that it is known in barcodes to include various information including type, volume, and concentration of a drug; expiration data of the device or drug; manufacture data of the device or drug; and other information such as serial numbers, lot numbers, hospital name, clinician name, and patient name. Manufacturing data commonly includes date and time of manufacture. See also Algazi where it is taught

"Unlike ordinary stamps and other forms of marking, secure, machine-readable portable data file barcode digital stamps can embed additional information such as the name of the sender (individual or corporate operator); the point of origin (home address or mailer ID); computer/printer serial number ID; credit card number, where applicable; and date/time stamp, tracked with the destination zip code at the delivery processing point. Secure digital mail stamps are printed communications protocols, capable of carrying a kilobyte of data in a square inch, and instantly readable by laser scanning or imaging devices; all commercially available and in use worldwide.

Clearly, Heinonen *et al.* in view of Flaherty and Algazi teaches that barcodes can be used on test strips, and the data can include time data such as manufacturing data and expiration data. Date and time data information would be beneficial as certain test strips, such as that taught by Robinson, Jr., include reagents whose "shelf-life" may be limited so that they are not effective

in the detection of biological materials if the test strips are used after the expiration date.

With regard to claim 7 it would have been obvious to mount the bio-hazardous indicator on the back side of the envelope as a) Robinson, Jr. already teaches that the location of the indicator is irrelevant as long as it can be seen and b) an indicator placed on the back side space would not cause any interference with existing automated mail processing equipment.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the teachings of Robinson, Jr. with the teachings of Weisenberg *et al.*, Applebaum, and/or Simon, along with the teachings of Heinonen *et al.*, Flaherty, and Algazi to provide an envelope with a plurality of holes along with a bio-hazard material indicator with an identifier associated with time.

5. Claims 3-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Robinson, Jr. in view of Weisenberg *et al.*, Applebaum, and/or Simon, along with the teachings of Heinonen *et al.*, Flaherty, and Algazi as applied to claims 1 and 2 above, and further in view of United States Patent 4,840,919 to Attar.

Robinson, Jr. in view of Weisenberg *et al.*, Applebaum, and/or Simon, along with Heinonen *et al.*, Flaherty, and Algazi teaches an envelope with a bio-hazardous material indicator. Robinson, Jr. in view of Weisenberg *et al.*, Applebaum, and/or Simon, along with Heinonen *et al.*, Flaherty, and Algazi

does not teach the use of a bio-hazardous material indicator where the holder can move while positioned inside the envelope.

First, making the holder and the substrate separable from the envelope would have been obvious, especially in view of the fact that the envelope does not inherently come with the indicator – it must be applied at some point in the manufacturing process. That is, the envelope and the biohazardous material indicator are already separate prior to attaching to the envelope. See also MPEP 2144.04 and *In re Dulberg*, 289 F.2d 522, 523, 129 USPQ 348, 349 (CCPA 1961) (The claimed structure, a lipstick holder with a removable cap, was fully met by the prior art except that in the prior art the cap is “press fitted” and therefore not manually removable. The court held that “if it were considered desirable for any reason to obtain access to the end of [the prior art’s] holder to which the cap is applied, it would be obvious to make the cap removable for that purpose.”).

To further support this obviousness, Attar teaches a bio-hazardous material indicator as seen in figures 1 and 2. The indicator comprises a base (reference item 12) that operates as a holder, a cover (reference item 14) with an opening (reference item 14a), and a substrate (reference item 22). The substrate is an acid base that can have a pH less than 4.5 capable of undergoing a visible change, i.e. a color change, in the presence of amines. Placing this device (or a device whose substrate is coated with the materials from Robinson, Jr.) into an envelope such as the ones taught by Weisenberg *et*

al., Applebaum, and/or Simon would allow existing envelopes to be used for the detection of possible anthrax contamination. Since these envelopes have a plurality of holes and Robinson, Jr. already teaches that the location of the indicator is irrelevant as long as it can be seen, one would only need to look into the existing holes to examine the indicator strip for a color change.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the teachings of Robinson, Jr. in view of Weisenberg *et al.*, Applebaum, and/or Simon, along with Heinonen *et al.*, Flaherty, and Algazi with the teachings of Attar to provide a bio-hazardous material indicator on a holder that is smaller than an envelope, and then to place the indicator in an envelope to detect the presence of bio-hazardous mater.

Conclusion

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

a. United States Patent Application Publication 2002/0060247 to Krishnaswamy *et al.* discloses that it is known to use test strips with identifier codes, such as an expiration date, and that a barcode is reader is the preferred means to enter the data.

b. United States Patent Application Publication 2002/0123671 to Haaland discloses that it is known to use test strips with barcodes.

c. United States Patent Application Publication 2003/0111357 to Black discloses that it is known to place barcodes on test strips.

d. United States Patent Application Publication 2003/0075593 to Wood discloses an envelope comprising a plurality of visual indicators for detecting the presence of a bio-hazardous material.


d. United States Patent 4,205,043 to Esch *et al.* discloses a hazardous material indicator comprising a base (reference item 10) with holes (reference item 12), along with substrates (reference item 14) that undergo a visual change in the presence of hazardous materials.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Rogers whose telephone number is (571) 272-2205. The examiner can normally be reached on Monday - Friday (0730 - 1600).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Hezron E. Williams can be reached on (571) 272-2208. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.


HEZRON WILLIAMS
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 2800

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

da 
May 4, 2004